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December 5, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

Pursuant to Case Management Order No. 12 (Dkt. 185), as modified by subsequent email correspondence with the Court, the Manufacturer Defendants submit this letter brief setting forth their position regarding (i) the selection of ESI custodians, (ii) the identification of search terms that will be used to search the selected custodians' ESI, and (iii) disputes pertaining to Plaintiffs' Requests for Production of Documents.[1]

I. Preliminary Statement

Plaintiffs approach discovery as if proportionality and undue burden have been eliminated from the Federal Rules. Despite the Court's recent warning that Plaintiffs do not have "free reign to discovery," Plaintiffs seek to require the Manufacturer Defendants to collect, search, and review ESI from the files of ***over 300*** custodians during time periods ranging from six to nine years. 11/20/19 Tr. at 9:16–17. Plaintiffs propose that these 300+ custodial files be searched with 485 search terms and 96 modifiers, many of which are overbroad and *not even limited to the product at issue:* valsartan. And Plaintiffs have still failed to "sharpen their pencils" with regard to their 115+

[1] The positions expressed in this letter are those of the Manufacturer Defendants. For that reason, references to "Defendants" throughout this letter brief refer to the Manufacturer Defendants only.

document requests, most of which remain facially overbroad despite repeated warnings from the Court. Combined, Plaintiffs' document requests and proposals for custodians and search terms are not just facially unreasonable; they border on absurd, and they flout the Court's recent ruling that it will not "approve duplicative, unnecessary, cumulative, and unduly burdensome discovery" simply because this may become a large MDL. 11/20/19 Tr. at 6:15-7:2.

If that were not enough, Plaintiffs have sprung many of these unreasonable requests on the Manufacturer Defendants within only the last few weeks. For months, Plaintiffs have received a steady stream of information in the form of core discovery, meet and confers, and an informal day-long interview with a defendant's corporate representative. In good faith, the Manufacturer Defendants conducted the appropriate due diligence and identified for Plaintiffs the ESI custodians who are most likely to have information relevant to this litigation. To date, the Manufacturer Defendants have offered 125 custodians based on their thorough investigations.[2] During that time, as to certain Defendants, Plaintiffs identified or asked about only short lists of possible custodians. Then, in mid-November, Plaintiffs sprung ***hundreds*** of new proposed custodians on the Manufacturer Defendants, often without any reasonable basis to believe that those individuals had any involvement with valsartan. In some meet and confers, Plaintiffs have refused to provide any justification for their proposed list, instead insisting that Defendants collect detailed employment histories or conduct a comprehensive comparison of custodial files before Plaintiffs would consider removing any custodian from their list. Plaintiffs' approach to custodian identification has not been reasonable, proportional to the needs of this case, or supported by the case law.

With respect to the search terms, the story is the same. After serving their initial list of search terms in September, Plaintiffs largely refused to compromise when the Manufacturer Defendants repeatedly explained the unworkability of Plaintiffs' proposals and offered different approaches that would result in comprehensive, but targeted, searching. Other than altering certain individual terms, Plaintiffs continuously rejected or simply did not commit to these proposals without offering any ideas of their own. In fact, they did not serve a new proposal until last week, when they sent their current search term list to the Manufacturer Defendants—at nearly 8:00 p.m. on November 27, the night before Thanksgiving. As with their mid-November and ongoing proffer of custodians, Plaintiffs' delay in making a meaningful counter-proposal is inexcusable. The Court has long stated that the parties must resolve all outstanding disputes by December 11, and Plaintiffs received through core discovery the "key information" necessary to "focus and narrow" discovery ***over five months ago***. 11/20/19 Tr. at 12:6-8.

Plaintiffs have followed this same pattern with the Requests for Production. After receiving Defendants' Amended Objections and participating in numerous meet and confers, Plaintiffs served a set of Amended Requests for Production on November 29, essentially re-framing the conversation on document production. After the Court observed that Plaintiffs needed to further "sharpen their pencils" for these requests, Plaintiffs served a second set of Amended Requests today, December 5,

[2] ZHP has proposed 35 custodians; Mylan has proposed 27; Teva has proposed 32; Torrent has proposed 18; and Aurolife and Aurobindo Pharma USA, Inc. have proposed 13.

the day the parties have agreed to submit briefing on discovery issues, and the second set of amendments was no narrower than their first attempted amendments. Defendants maintain their Amended Objections and do not waive them with respect to either the original Requests for Production or the Amended Requests. Defendants reserve the right to object to any and all of the Amended Requests served on December 5 and plan to will address additional issues, including those Plaintiffs raise in their opening brief and others identified by Defendants upon additional review of the second set of Amended Requests, by way of the response on December 9.

In short, Plaintiffs' repeated and tactical delay and their exceedingly broad discovery requests, custodians, and search term proposals should be rejected for what they are: an abuse of the discovery process. "Adversarial discovery practice, particularly in the context of ESI, is anathema to the principles underlying the Federal Rules." *Webasto Thermo & Comfort North America, Inc., v. BesTop, Inc.*, 326 F.R.D. 465, 469 (E.D. Mich. 2018) (denying facially unreasonable search terms). Plaintiffs have offered no plausible reason why the Manufacturer Defendants' proposed custodians and proposed search protocol would result in anything but a comprehensive production of material, probative documents. Once again, "to secure the just, speedy, and inexpensive determination of this litigation," the Court should not give Plaintiffs "everything they ask for." 11/20/19 Tr. at 8:3–5.

II. Plaintiffs are not entitled to receive every document in Defendants' possession that potentially relates to valsartan.

Although "the right to discovery is … broad, it is not unlimited, and courts may in the exercise of their discretion deny 'unreasonably cumulative' discovery requests." *City of Sterling Heights Gen. Emples. Ret. Sys. v. Prudential Fin., Inc.*, No. 12-05275, 2015 U.S. Dist. LEXIS 110712, at *6 (D.N.J. Aug. 21, 2015) (citing *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999)). The Court in this litigation explicitly instructed that Plaintiffs will not be given "free reign to discovery," and that the Court "must reasonably limit plaintiffs' discovery in order to prevent duplicative, cumulative, and minimally important discovery." 11/20/19 Tr. at 8:12-14, 9:16-17. That standard applies equally to the identification of ESI custodians and search terms. The scope of "collection, review and production of ESI 'present[s] special challenges' that standard discovery disputes do not, including the substantial likelihood that the data possessed by the responding party is voluminous, stored in multiple formats, and is duplicative across custodians." *Blackrock Allocation Target Shares: Series S. Portfolio v. Bank of New York Melon*, No. 14-9372, 2018 WL 2215510, at *7 (S.D.N.Y. May 15, 2018) (quoting *Winfield v. City of New York*, No. 15-5236, 2017 WL 5664852, at *7 (S.D.N.Y. Nov. 27, 2017)). Thus, the "emergence of e-discovery only has intensified the need for judicial scrutiny of the scope of discovery," as the "information explosion of recent decades … has greatly increased both the potential cost of wide-ranging discovery and the potential for discovery to be used as an instrument for delay or oppression." *Sterling Heights*, 2015 U.S. Dist. LEXIS 110712 at *7 (quoting Advisory Committee Note to Fed. R. Civ. P. 26).

The Federal Rules, therefore, ***do not*** entitle Plaintiffs to every potentially relevant document held by every employee. There "is no obligation on the part of a responding party to examine every

scrap of paper in its potentially voluminous files," especially in "an era where vast amounts of electronic information is available for review." *Enslin v. Coca-Cola Co.*, No. 14-06476, 2016 U.S. Dist. LEXIS 193556, at *8 (E.D. Pa. June 8, 2016) (quoting *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec.*, 685 F. Supp. 2d 456, 461 (S.D.N.Y. 2010)). "It must … be remembered that the Federal Rules of Civil Procedure require *only a reasonable search* for responsive information pursuant to a '*reasonably comprehensive search strategy*.'" *Id.* (emphasis added) (quoting *Treppel v. Biovail Corp.*, 233 F.R.D. 363, 374 (S.D.N.Y. 2006)). In fact, "the right to even plainly relevant discovery is not limitless." *Lauris v. Novartis AG*, No. 16-00393, 2016 WL 7178602, at *4 (E.D. Cal. Dec. 8, 2016). Accordingly, courts reject untargeted, sweeping requests for custodians and search terms as inappropriate and disproportionately burdensome. *See, e.g., Firefighters' Ret. Sys. v. Citco Grp., Ltd.*, No. 13-373, 2018 WL 276941, at *6 (M.D. La. Jan. 3, 2018) (rejecting plaintiffs' lengthy custodian list "as a request to somehow ensure that every single potentially responsive document (no matter how cumulative or burdensome to obtain) should be produced"); *Webasto*, 326 F.R.D. at 468 (rejecting proposed search term list as overbroad).

Furthermore, as the "part[ies] who [are] asked to produce ESI," the Defendants are "best situated to evaluate the procedures, methodologies, and technologies appropriate for … producing [their] own electronically stored information." *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *2; *accord Firefighters' Ret. Sys. v. Citco Grp. Ltd.*, No. 13-373, 2018 WL 276941, at *4 (M.D. La. Jan. 3, 2018); The Sedona Principles, Third Edition, 19 Sedona Conf. J. 1, 52 (2018). That is what the Manufacturer Defendants did. They proposed lists of ESI custodians designed "to respond fully to Plaintiff[s'] requests and produce responsive, non-duplicative documents covering the entire time period." *Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168, 2012 WL 1299379 at *9 (D.N.J. Apr. 16, 2012) (denying request to expand custodian list). And they have proposed a search term list that will identify the relevant, responsive documents without resulting in a high number of irrelevant hits that must be reviewed and weeded out before production. Simply put, there is no reason to believe that Defendants' proposed custodians and search protocol will result in anything but a comprehensive production of documents responsive to Plaintiffs' extensive and varied requests.

III. The Manufacturer Defendants have proposed as ESI custodians the key employees who possess the vast majority of the relevant documents related to valsartan.

A. Procedural History

Pursuant to Case Management Order No. 12 (Dkt. 185), on September 23, 2019 the Manufacturer Defendants sent proposed lists of ESI custodians to Plaintiffs.[3] Together, these original lists identified 39 custodians who—based on counsels' investigation with their respective clients—were closely involved with the manufacturing process, testing, sales, and regulatory functions at issue related to valsartan.

[3] The Court permitted Defendants a one-week extension, which was uncontested by Plaintiffs, from September 16 to September 23 to identify custodians. *See* 9/12/19 Tr. at 6:11-7:2.

Plaintiffs responded on October 3, 2019, by sending a letter requesting that the Manufacturer Defendants identify employees with "primary responsibility to assess the contamination issue, whether from a testing, regulatory, investigation, [or] marketing standpoint," "employees who were involved in and made the decisions with regard to the manufacturing process," "employees who would be most knowledgeable regarding testing," "employees and/or other persons/entities who were responsible for investigating and determining the root cause or causes of the contamination, and, "[w]ith regard to finished dose manufacturing, and distributors," the employees "responsible for or involved in testing the API." *See* Exhibit B at 3–4.

The parties then engaged in a lengthy meet-and-confer process regarding company structure and appropriate ESI custodians, starting with an in-person meeting at Duane Morris' offices on October 7. During these meet and confers, each of the Manufacturer Defendants explained how their original 39 proffered custodians covered, by job responsibility and duration of employment, each of the areas identified in Plaintiffs' October 3 letter referenced and quoted above. Plaintiffs followed up by identifying a few potential additional custodians for each Manufacturer Defendant, and the parties continued meeting and conferring about the scope of Defendants' ESI custodian lists throughout October.[4] As a result of these many meet and confers, each Manufacturer Defendant expanded its list of proposed ESI custodians to include additional employees, bringing the total from 39 to 125.

Although the Court originally ordered Plaintiffs to serve their "proposed additions/deletions" to the Manufacturer Defendants' custodian lists by October 15, *see* Dkt. 185, ¶ 6, by November 6, Plaintiffs had not indicated whether they agreed to any of the Defendants' proposals or whether they still believed the lists compiled as of that date were insufficient. Concerned about being provided with a long list of new proposals close to December 11, the Manufacturer Defendants requested the Court to require Plaintiffs to serve up-to-date custodian lists in a timely fashion to enable the parties to negotiate the lists before December 11. *See* Nov. 6 Tr. at 21:22–23:2. Plaintiffs denied having undisclosed custodian lists, stating that they had disclosed "the names [Plaintiffs] have" and had "asked about" all of them during the meet and confers. *Id.* at 23:23–24:4. But just six days later—after being ordered to do so by the Court—Plaintiffs began to send the Manufacturer Defendants proposals to add ***hundreds*** of new custodians.

As this Court noted during the November 20, 2019 hearing, "the purpose of ordering core discovery was to get in plaintiffs' hands early in the case key information to enable plaintiffs to

[4] For example, on October 8, Plaintiffs sent the ZHP Defendants a list proposing 17 additional custodians, only 6 of whom were correctly identified as ZHP employees. *See* Exhibit C. At the time, only ZHP itself was negotiating custodians, as Plaintiffs had not directed any document requests towards non-manufacturer Defendants. The ZHP Defendants have agreed to add four custodians identified in that list, and have explained to Plaintiffs in follow-up correspondence why the others are inappropriate custodians. After October 8, Plaintiffs did not propose any additional ZHP custodians until November 12, when they sent ZHP a list of ***141 "preliminary" custodians***, which they then increased to ***159*** one week later.

focus and narrow their discovery requests." 11/20/19 Tr. at 12:5-8. Yet Plaintiffs have done the opposite. Despite having received extensive core discovery and organizational charts, and despite the opportunity to informally question a corporate representative for *five hours*,[5] in many instances Plaintiffs have resorted to demanding additional custodians for no reason other than that the individual lists a Manufacturer Defendant as an employer on LinkedIn or is mentioned on a Manufacturer Defendant's website—without *any* regard to whether the individuals have any involvement with valsartan, let alone the manufacturing issues at the heart of this litigation. Plaintiffs have named potential custodians without any reason to believe that the individual has material, non-duplicative relevant information. In fact, many of their proposed custodians do not appear in *any* of the hundreds of thousands of pages of core discovery, and instead were apparently added as a result of an indiscriminate internet search.[6]

B. The case law does not support Plaintiffs' demand for such burdensome and duplicative proposed custodians.

Because the responding party is in the best position to identify the appropriate custodians, courts require the requesting party to show that the "additional custodians possess relevant, *non-duplicative* ESI" not captured by searches of the responding party's identified custodians. *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *4 (emphasis added); *accord Sterling Heights*, 2015 U.S. Dist. LEXIS 110712 at *9 (requiring plaintiff to show that additional custodians would "yield unique, noncumulative documents"); *Arconic Inc. v. Novelis Inc.*, No. 17-1434, 2019 U.S. Dist. LEXIS 195213, at *60 (W.D. Pa. Sep. 6, 2019) (denying request to add custodians because plaintiff failed to "demonstrate that any proposed custodian possesses unique information not covered by other … custodians"). Plaintiffs "therefore bear[] the burden" of showing that the Manufacturer Defendants' proposed custodians are "inadequate and that additional efforts are warranted." *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *2-3. Furthermore, it is not enough for Plaintiffs to merely suggest the custodian "had some relation to the events in question," or to assert "in conclusory fashion" that their proposed custodians are "knowledgeable and possess[] relevant information about the facts and claims at issue." *Id.* at *6. To warrant *additional* custodians, Plaintiffs must "be able to articulate a basis for the court to find that ESI in the possession of the additional custodians would be different

[5] Plaintiffs were provided a full day to informally meet with a representative of the ZHP Defendants, Mr. Jun Du, in Court in the presence of Your Honor, about the ZHP party ESI custodians. They ended the meeting on their own volition after five hours, the four Plaintiffs' counsel present having each exhausted their individual lines of questioning of Mr. Du about the ZHP party custodians. As discussed further below, Plaintiffs asked questions about only 6 of the 88 individuals they currently seek to add as custodians.

[6] Given that these individuals were identified using public internet searches, there is no reason why Plaintiffs could not have previously identified these individuals by October 15th, as ordered by the Court.

from, and not simply duplicative of, information" within the possession of the existing custodians. *Id.* at *6.

Plaintiffs have made no such showing. The Manufacturer Defendants have proposed reasonable lists of key employees whose custodial files are most likely to possess the relevant, probative documents. There is no reason to believe that Plaintiffs' proposed additions will add anything but cumulative ESI that will already be collected and produced through searches of the Defendants' proposed custodians. *See, e.g., Breuder v. Bd. of Tr. of Cmt. Coll. Dist. 502, DuPage Cty., Ill.*, No. 15-9323, 2019 WL 3386966, at *7 (Jul. 26, 2019) (denying request to add custodians because none "were decisionmakers with respect to the decisions that impacted plaintiff and all of them … reported to individuals who are already custodians); *Arconic*, 2019 U.S. Dist. LEXIS 195213, at *63–64 (denying request to add custodian because employee "was working at the direction of" an existing custodian and there was "no showing" that existing custodian was "unlikely to possess in his files the information most relevant" to plaintiff's "stated need").

Finally, Plaintiffs' attempt to expand the number of Manufacturer Defendant custodians from approximately 125 to over 300 will dramatically increase the costs of ESI discovery. Searching, reviewing, and producing ESI "from each additional custodian" creates "sizeable costs." *Sterling Heights*, 2015 U.S. Dist. LEXIS 110712 at *9. Even with the use of de-duping technology to reduce the number of duplicative documents actually produced, the "proffered custodians' data must be located, collected, processed, and searched," which is "extraordinarily expensive and inefficient." *Arconic*, 2019 U.S. Dist. LEXIS 195213, at *60 n.9; *see also Mann v. City of Chicago*, No. 15-9197, 2017 WL 3970592, at *5 (N.D. Ill. Sept. 8, 2017) (denying plaintiffs' request for additional custodians, noting that "every additional custodian increases the risk of duplication of emails and the time and resources necessary to review emails"). This is especially true given the lengthy relevant time periods ordered by the Court, ranging from six to nine years. And for ZHP, whose documents are located in China, there is the extra cost and burden of an additional level of review to ensure compliance with the Guarding of State Secrets Law. *See* Law on Guarding State Secrets of the People's Republic of China 1988 as revised in 2010, Order No. 6 of the President of the People's Republic of China. The Manufacturing Defendants should not be required to undertake the time, expense, and burden of searching the files of all of Plaintiffs' proposed custodians, when Plaintiffs cannot even proffer any reason why the custodians proposed by the Manufacturer Defendants are insufficient.

C. Defendant-Specific Issues

1. The ZHP Defendants

a. The ZHP Defendants have proposed 35 key employees who possess the relevant, probative documents responsive to Plaintiffs' requests.

As responding parties, the ZHP Defendants are "best situated to evaluate the procedures, methodologies, and technologies appropriate for … producing [their] own electronically stored

information." *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *2; *accord* 19 Sedona Conf. J. at 52. After a thorough investigation, the ZHP Defendants have identified 35 key employees who possess the relevant, probative documents responsive to Plaintiffs' requests. These employees have worked closely with valsartan in capacities related to process development, production, quality assurance, quality control, regulatory affairs, and sales. They include:

- Five employees within ZHP's API Quality Assurance department at the Chuannan API manufacturing facility, who are responsible for, among other things, quality assurance oversight for valsartan API; reviewing and approving cGMP procedures; conducting the nitrosamine root cause investigation; reviewing deviation investigation reports for valsartan API; overseeing the 2013 manufacturing process change from a quality-assurance perspective; communicating with customers about the nitrosamine impurities; reviewing and approving SOPs; and overseeing qualification of vendors, including for solvents used in valsartan.
- Three employees within ZHP's API Quality Research department, who are responsible for, among other things, researching and developing the analytical methods for testing valsartan, including the testing methods used to identify nitrosamines.
- Two employees within ZHP's API Quality Control department at the Chuannan facility, who are responsible for researching and implementing the testing conducted on valsartan API and who oversee the analytical lab where the testing occurs, including chromatographic impurity testing and testing for residual solvents.
- Three employees within ZHP's API Production department at Chuannan, who are responsible for overseeing the manufacture of valsartan API.
- One employee within ZHP's API Technology department, who was the ZHP employee primarily responsible for development of the 2013 manufacturing process change at issue. This employee also works closely with the equipment and raw materials, including solvents, used in the manufacture of valsartan API.
- Four employees within ZHP's API Regulatory Affairs department, who are responsible for submitting regulatory filings for valsartan API, including all of those relating to valsartan manufacturing and the valsartan recall.
- Five employees within ZHP's API Sales department, who are responsible for communicating with ZHP's valsartan API customers, including the other Defendants in this action.
- Four employees within ZHP's Procurement department, who are responsible for procuring the raw materials used in valsartan API.
- One employee who oversees ZHP's Finished Dose Quality Assurance and Finished Dose Quality Control departments at the Xunqiao finished dose manufacturing

facility, who is responsible for, among other things, reviewing and approving cGMP procedures and overseeing testing.

- One employee within ZHP's Finished Dose Technology department, who is responsible for, among other things, process development for the valsartan finished dose manufacturing process.
- Three employees at Solco, who are responsible for sales of valsartan finished dose products in the United States, including communications to customers.
- Three employees at Prinston, who are responsible for research and development, regulatory affairs, and quality assurance related to valsartan finished dose products marketed in the United States.
- One employee at Huahai U.S., who has been involved in the sale of research samples of valsartan API to customers based in the United States.[7]

As even the abridged descriptions above demonstrate, the ZHP Defendants have proposed custodians designed "to respond fully to Plaintiff[s'] requests and produce responsive, non-duplicative documents covering the entire time period." *Eisai*, 2012 WL 1299379 at *9.[8] Furthermore, Plaintiffs had ample opportunity to question Jun Du, a corporate representative of the ZHP parties, during an informal meeting on October 23 before the Court. Plaintiffs questioned Mr. Du for five hours about the ZHP companies and the employees who were responsible for various aspects of valsartan manufacturing and quality oversight. Mr. Du's answers to their questions were fully consistent with the list above.

b. Plaintiffs propose an additional 88 custodians but have not demonstrated the necessity of a single one of them.

After proposing 17 potential custodians on October 8—only six of whom were ZHP employees—Plaintiffs did not propose a single additional custodian until November 12, after the Court ordered them to do so. On November 12, Plaintiffs proposed a list of ***141*** custodians. *See* Exhibit D. In a subsequent letter sent November 25, Plaintiffs further expanded their list to ***159 custodians***.[9] *See* Exhibit G. Although the parties had met many times since October 8, including

[7] Because one of ZHP's proposed custodians is a member of two departments, he appears twice in this list.

[8] More extensive details about each of the proposed custodians are provided in the November 27 letter attached as Exhibit H. In addition, the ZHP Defendants can provide more detailed factual context about each of Plaintiffs' 136 proposed custodians should the Court find that granular information helpful.

[9] Although the ZHP Defendants later identified 11 instances where Plaintiffs listed the same employee more than once, the fact stands that Plaintiffs believed they were serving a list of 159

with Mr. Du on October 23, Plaintiffs raised the vast majority of these individuals for the first time in this series of November letters. In fact, on October 23, Plaintiffs asked Mr. Du about ***only six*** employees not already proposed by the ZHP Defendants as custodians. *See* Exhibit D (identifying in "Proffered By" column of attached chart only six employees discussed on 10/23/19).[10] After some winnowing down and removal of individuals that Plaintiffs inadvertently listed more than once, Plaintiffs currently propose adding 88 custodians to the ZHP Defendants' list, for ***a total of 123 "preliminary" custodians***—double the number sought from any other Defendant. This list does not currently include Plaintiffs' proposals related to ZHP's Xunqiao finished dose facility.

Plaintiffs have not demonstrated the necessity of a single one of their 88 proposed additions. The ZHP Defendants have explained to Plaintiffs telephonically and in two substantive letters why, both legally and factually, Plaintiffs' list is unreasonable and unsupported. *See* Exhibits E and H. Plaintiffs have responded by largely refusing to remove custodians (in fact, they added to their list as recently as December 2), and by refusing to engage in a substantive conversation designed to provide explanation for the expansion of their custodian list. Despite the Court's warning that this process "has to be a two-way street," *see* 11/6/19 Tr. at 25:7-8, Plaintiffs have refused to discuss their rationale for removing or adding custodians and have refused to address the objections raised in the ZHP Defendants' letters. In fact, when asked during a November 25 meet and confer, Plaintiffs stated that they would not be providing ***any*** explanation for why they believe that the ZHP Defendants' proposed list is inadequate, or why they believe that any of their 88 newly proposed individuals are either appropriate or necessary.

Instead, Plaintiffs have taken the position that once they name an employee at ZHP or any of its subsidiaries, ZHP has the burden of showing that the employee will not have responsive, non-duplicative ESI. Plaintiffs have refused to remove an employee unless the ZHP Defendants collect detailed employment information, including all titles ever held at ZHP companies, dates of employment, and description of involvement with valsartan, and show that the employee had no involvement with valsartan over the past ten years. That position flips Plaintiffs' burden on its head. *See Enslin*, 2016 U.S. Dist. LEXIS 193556 (holding that requesting party has burden of showing "additional custodians possess relevant, non-duplicative ESI"); *Sterling Heights*, 2015 U.S. Dist. LEXIS 110712 at *9 (same); *Arconic*, 2019 U.S. Dist. LEXIS 195213 (same). As the requesting party, Plaintiffs have the burden to show relevance and to demonstrate that their proposed additions have responsive, non-duplicative ESI. Plaintiffs have failed to do so, instead proposing any name they can find on any document in ZHP's core discovery productions.

Plaintiffs' attempted burden-flip is especially unreasonable because Plaintiffs delayed providing their new lists until mid-November and after, including even into December, and then

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individuals as the "preliminary" custodians for ESI discovery, "reserving their right" to add even more custodians.

[10] As noted on the chart, Plaintiffs also asked Mr. Du questions about three third-party consultants, whom Plaintiffs have since agreed to eliminate from their custodian list.

resorted to naming 26 individuals based only on LinkedIn profiles and company websites[11] and 22 based solely the individual's appearance on an organizational chart, without any reasonable basis to believe those individuals have any connection to valsartan or the issues in these actions. Plaintiffs' unreasonable requests have imposed significant costs on the ZHP companies, who had employees work overtime to pull together employment information in time to continue meeting and conferring before the briefing deadlines. ZHP's counsel incorporated that information into the 18-page letter sent on November 27. *See* Exhibit H. But Plaintiffs remain unsatisfied, calling the information "basic" and "far too limited" to allow them to meaningfully reduce their custodian list. Exhibit I at 1–2. Similarly, Plaintiffs have refused to eliminate employees who are supervisors of or subordinates to existing custodians unless ZHP "investigates" those employees "and finds that a superior should have received *every relevant document* produced or received by their subordinate." *See* Exhibit F at 1. In other words, Plaintiffs admit that their lengthy custodian list is "a request to somehow ensure that every single potentially responsive document (no matter how cumulative or burdensome to obtain) should be produced." *Firefighters' Ret. Sys.*, 2018 WL 276941, at *6 (denying request to expand custodian list). Plaintiffs' list should be rejected for what it is: an abuse of the discovery process that will only impede the production of relevant, non-cumulative information.

In addition, Plaintiffs' position ignores the reality of large pharmaceutical companies like ZHP. ZHP manufactures between 20 and 30 APIs and employs over 1,000 individuals at its Chuannan facility alone. A significant number of these employees are not assigned to a specific drug. For example, ZHP employs approximately 290 analysts to conduct testing: 120 in the Chuannan Quality Control department, and 170 in the Xunqiao Quality Control department. Analysts are not assigned to a specific drug and instead have varied assignments based on their availability on any given day. Mr. Du explained these facts to Plaintiffs on October 23, and ZHP's counsel has reiterated them to Plaintiffs on several occasions. Yet Plaintiffs have sought to add employees as custodians simply because their names appear on a single chromatogram produced during core discovery and have refused to remove those individuals unless ZHP can attest that they had "no involvement" with valsartan.

In truth, a significant number of ZHP employees have worked on valsartan in some way during the past 10 years. In addition to the hundreds of employees who conduct testing, each production workshop employs between 20 and 80 employees who are on the ground operating the machines that manufacture the APIs. ZHP manufactures valsartan API in four workshops, meaning that anywhere from 80 to 320 employees work on valsartan at the manufacturing level. And that number does not include the managers assigned to those workshops, or the directors supervising the managers, or the quality assurance personnel who are in the room observing each step of the process.

[11] Plaintiffs have since withdrawn 20 of the 26 employees whom they named based solely on their identification on LinkedIn or company websites, but not before ZHP expended significant resources collecting employment information about each of them.

Of course, ZHP is not unique. These are simply the realities of a modern corporation. For that reason, the standard for identifying a custodian is not that the individual had *some* involvement with "the events in question" or "possesses relevant information about the facts and claims at issue." *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *6. The standard is whether the nature of the employee's role, and the degree of the employee's involvement with key issues, provide a reasonable basis to believe that the individual possesses material, probative information. *See Lauris*, 2016 WL 7178602, at *4 (approving of defendants' list of "nine key employees who had primary roles in evaluation of the scientific data regarding Tasigna and the potential risk of atherosclerosis"). Those are the individuals whom the ZHP Defendants have identified as custodians: the employees who had primary roles in key aspects of valsartan, including development of the API manufacturing process, development and implementation of testing methods, oversight of quality assurance and cGMP protocols, communications with regulators and customers, and oversight of the root cause analysis into the nitrosamine impurities.

Thus, and for *inter alia* the following reasons, articulated in greater detail in ZHP's November 14 and 27 letters, Plaintiffs have failed to meet their burden of showing that any additional custodians are necessary.

- **Plaintiffs' proposed custodians include individuals who are duplicative and likely to have cumulative ESI.**
    - High-level executives. Plaintiffs seek to add several high-level executives who are not involved in the day-to-day details of valsartan production, testing, or quality assurance activities. Because of their status as high-level employees, those individuals will likely have less probative, and mostly derivative, cumulative, information when compared to the custodians that ZHP already proposes, who were chosen specifically because they are the employees most involved with and knowledgeable about the relevant issues.
    - Subordinates of existing custodians. Similarly, Plaintiffs propose many individuals who are subordinates to existing custodians, and thus are unlikely to be a decision-maker or to have relevant, noncumulative documents. *See Brueder*, 2019 WL 3386966 at *7 (declining to order defendant to add custodians where "[n]one of the proposed new custodians were decisionmakers with respect to the decisions that impacted plaintiff and all of them … reported to individuals who are already custodians"). As noted above, ZHP identified as custodians those most involved with and knowledgeable about the relevant issues.
    - Individuals with facially duplicative descriptions. Plaintiffs' list includes individuals whose only proffered justification is identical—e.g., they reviewed the same document or attended the same meeting. For example, Plaintiffs seek to have as custodians all 18 attendees of a closeout meeting that occurred during the May 2017 FDA inspection of the Chuannan facility,

before the recall. But ZHP has already proposed 11 of those attendees as custodians, based on ZHP's determination that those individuals worked most closely with valsartan and with the alleged impurities.[12] Similarly, as part of ZHP's quality assurance protocols, validation reports are reviewed and approved by multiple individuals. In many instances, Plaintiffs seek to add multiple people who reviewed the same validation report. Plaintiffs "are not entitled to every single document," or every single copy of a relevant document. *Blackrock*, 2018 WL 2215510, at *10. Rather, the "selection of custodians [for ESI discovery] must be designed to respond fully to document requests and to produce responsive, *nonduplicative documents* during the relevant time period." *Breuder*, 2019 WL 3386966, at *6 (emphasis added, internal punctuation and citation omitted); *see also Blackrock*, 2018 WL 2215510, at *10 (declining to add custodians absent showing that they "possessed unique, relevant documents") (original emphasis).

- **Plaintiffs' proposed custodians include individuals who are not proportional due to time frame.**
    - ZHP selected custodians who have worked closely with key aspects of valsartan throughout the relevant time period ordered by the Court. For example, the five API Sales employees proposed by ZHP have a collective 41 years of experience at the company. With one exception, they all began working with ZHP years before ZHP sold any valsartan API for use in a product that could have been sold into the United States (*i.e.*, sold to a company with an approved valsartan ANDA). In the one instance where a proposed custodian was hired only recently, ZHP also proposed his subordinate for completeness, who has been employed since 2013. Nevertheless, in this department and in others, Plaintiffs seek to add custodians who were employed for much shorter periods. For example, Plaintiffs seek to add one of the current VPs of API Sales, even though (1) she has only been in that position since April 2019, and (2) ZHP has already proposed the other current VP of API Sales, who has been in that position since 2013.
- **Plaintiffs' proposed custodians include individuals who were immaterially involved with valsartan and thus unlikely to have ESI of the same quality as the ZHP Defendants' proposed custodians.**
    - In addition, Plaintiffs have refused to remove certain custodians even after the ZHP Defendants explained that they were minimally involved with valsartan. *See generally* Exhibit H (explaining how a significant number of

[12] The May 2017 FDA Chuannan inspection was not limited to valsartan, but also involved another drug.

> Plaintiffs' proposed custodians had immaterial or minimal involvement with valsartan). As explained above, there are many lower level employees who perform routine functions with respect to the manufacture and testing of valsartan, as well as many other APIs. There is simply no reason to include, for example, the individuals who performed chromatography as custodians where, as here, the chromatography test results will be produced from non-custodial sources and ZHP has proposed employees with decision-making authority regarding the results of those tests as ESI custodians. In addition, custodians with responsibilities like overseeing the warehouse, managing inventory, or filing patents will not have custodial information that is material to the alleged impurities at issue in this case.

In sum, the ZHP Defendants have proposed a comprehensive list of custodians who have been closely involved with all key aspects of valsartan. In their brief also filed today, Plaintiffs will surely repeat the familiar refrain that they lack sufficient information to select the best custodians. But that is not a reason to give Plaintiffs *carte blanche* to name custodians, or to require the Defendants to undergo the time and expense of collecting, searching, and reviewing hundreds of custodial files when *no party* has a reason to believe that such a process will result in the production of material, non-duplicative documents. And this case is no different than every other civil action filed in federal courts—*of course* the ZHP Defendants have better knowledge of their internal organization and their own employees. That is why courts defer to defendants' selection of reasonably comprehensive custodian lists. *See Enslin*, 2016 U.S. Dist. LEXIS 193556, at *2; 19 Sedona Conf. J. at 52. As happens in every case, as discovery proceeds, the parties may determine that searches of additional custodial files are warranted. If that occurs, Plaintiffs can request to add custodians by making a showing that the "additional custodians possess relevant, non-duplicative ESI." *Enslin*, 2016 U.S. Dist. LEXIS 193556, at *4; *accord Sterling Heights*, 2015 U.S. Dist. LEXIS 110712 at *9; *Arconic*, 2019 U.S. Dist. LEXIS 195213. That is how every case proceeds, and there is no reason to abandon that practice and allow Plaintiffs to dramatically expand the custodian list with little to no justification.

c. Limiting the preliminary list to 50 custodians is a reasonable compromise.

The ZHP Defendants maintain that the 35 custodians they have proposed are more than sufficient for a reasonable search. However, in the spirit of compromise, the ZHP Defendants have proposed limiting the preliminary custodian list to 50 individuals. *See* Exhibit H at 2–3, 18. That would allow Plaintiffs to *select an additional 15 employees*. Given Plaintiffs' inability to articulate why the ZHP Defendants' 35 proposed custodians are inadequate, this is more than reasonable. In addition, a 50-custodian limit is consistent with the number of custodians Plaintiffs have sought for each of the other Manufacturer Defendants. Plaintiffs have offered no explanation for why they need 123 custodians for the ZHP Defendants, but only half that many for the other companies. To the extent the Court is inclined to allow Plaintiffs any custodians in addition to the 35 proposed by the ZHP Defendants, the ZHP Defendants maintain that they should be limited to 50 total. Imposing a

limit on Plaintiffs' preliminary custodian list will also facilitate further meet and confers, and will hopefully enable ZHP and Plaintiffs to agree to the identity of the 50 custodians by December 18.

2. The Teva Defendants

The Teva Defendants initially proposed a list of 8 custodians, attempting to identify the most central individuals in possession of documents relevant to the issues in this litigation. Over the course of several discussions and the exchange of written lists, Plaintiffs and the Teva Defendants expanded this list to include 18 total custodians. Plaintiffs reviewed organizational charts and the core discovery documents provided by the Teva Defendants, and based on these materials proposed additions and deletions which resulted in a final proposal on November 25, 2019, of adding another 42 custodians. On December 4, 2019, the parties engaged in an extensive meet and confer to discuss these individuals, and the Teva Defendants agreed to add 14 more custodians.

Notably, of the 14 custodians the Teva Defendants have agreed to add, 9 were from Plaintiffs' proposed list, and 5 are custodians the Teva Defendants have identified during their continuing inquiry into those persons most likely to have relevant, non-duplicative documents, after discussions with Plaintiffs on the types of documents and information sought. As it currently stands, Teva has proposed a list of 32 custodians:

- 15 persons from across the Quality Group;
- 4 from Regulatory Affairs;
- 3 from Sales & Marketing;
- 3 from Procurement;
- 1 from Pharmaco-Vigilance;
- 2 from the Teva Defendants' Malta finished dose manufacturing facility;
- 2 from the Teva Defendants' Jerusalem finished dose manufacturing facility;
- 1 Toxicologist; and
- 1 employee in Commercial Operations.

The remaining custodians at issue principally fall into two categories: (1) individuals whom the Teva Defendants believe are duplicative of custodians already produced, and (2) persons in the sales and pricing function who may not have any unique information relevant to valsartan or the economic claims at issue. With respect to the purely duplicative custodians, the minimal chance of obtaining relevant, unique information or documents from these individuals is not proportional to

the needs of this litigation due to the burden associated with performing a full collection, search, and review of in many cases eight years of custodial document.

The Teva Defendants hope that Plaintiffs will agree the robust list of custodians identified thus far is adequate for purposes of collecting custodial documents in relation to entities solely involved at the finished dose level. In any event, the Teva Defendants continue to follow up on some additional names—a number of which were first identified to the Teva Defendants as potential additions on November 25, 2019—and aim to reach agreement on the custodian list by December 11, or at the very latest December 18.

3. The Torrent Defendants

The Torrent Defendants initially proposed a list of 8 custodians, who they believe are the most central individuals in possession of documents relevant to the issues in this litigation. On October 9, 2019, Plaintiffs proposed an additional 11 custodians based on documents produced during core discovery. Then, on November 18, 2019, Plaintiffs added an additional ***53*** custodians, bringing the total number of potential custodians to 62. On December 4, 2019, the parties engaged in a meet and confer to discuss these individuals. In the interest of cooperation, Torrent Defendants accepted 10 of plaintiffs proposed custodians that may have relevant information, bringing the total to 18 custodians.

As it currently stands, Torrent has proposed a list of 18 custodians:

- 6 persons from across the Quality Group;
- 5 from Regulatory Affairs;
- 3 from Sales & Marketing;
- 4 from Procurement;

The remaining custodians at issue principally fall into two categories: (1) individuals whom the Torrent Defendants believe are duplicative of custodians already produced, and (2) persons in roles who may not have any unique information relevant to valsartan or the claims at issue, for example, the manager of Gifts and Promotional Items. The Torrent Defendants hope that Plaintiffs will agree the list of custodians identified thus far is adequate for purposes of collecting custodial documents. In any event, the Torrent Defendants continue to follow up on some additional names and department functions and aim to reach agreement on the custodian list by December 11, or at the very latest December 18.

4. Aurolife Pharma LLC and Aurobindo Pharma USA, Inc.

Aurolife Pharma LLC ("Aurolife") and Aurobindo Pharma USA, Inc. ("APUSA") initially proposed a list of four (4) custodians comprised of employees from both companies who worked

closely with valsartan in capacities relating to quality control, manufacturing, regulatory affairs and quality assurance. Since then, counsel has engaged in multiple extensive meet-and-confers with Plaintiffs to discuss those individuals and others whom the Plaintiffs identified. Following their initial meet-and-confer, Aurolife agreed to add three (3) more custodians and APUSA agreed to add two (two) more custodians. These included three (3) additional employees in quality assurance and a pharmacovigilance manager. On October 15, 2019, Aurolife and APUSA produced organizational charts and asked Plaintiffs to let counsel know if they believed any other names should be included on the list of custodians. Approximately one month later, on November 15, 2019, Plaintiffs sent defense counsel a list of nineteen (19) individuals, proposing that they be added to the list of custodians. Two of those were individuals that the parties had already agreed on. Eight of them were employees of Aurobindo Pharma Ltd. and *not* Aurolife or APUSA.

Plaintiffs agreed to stand down on the individuals employed by Aurobindo Pharma Ltd. The parties have been meeting-and-conferring on the remaining nine (9) that Plaintiffs identified. Of those, Aurolife and APUSA agreed to add three (3) to the list of custodians. In addition, Aurolife agreed to add one individual who Plaintiffs did not include on their list. That person was identified through Defendants' ongoing inquiry into those persons most likely to have relevant, non-duplicative documents, after discussions with Plaintiffs on the types of documents and information sought. Currently, the parties' agreed-upon list includes thirteen (13) custodians, including five (5) from Quality Assurance, one (1) from Quality Control, one (1) from Regulatory Affairs, one (1) from Pharmacovigilance, two (2) from Procurement, and three (3) from Manufacturing and Testing.

The other individuals are being disputed because they were not actively involved with the products at issue or the recall and/or they are duplicative of custodians that the parties already agreed-to. Aurolife and APUSA hope that Plaintiffs will agree the current list of thirteen (13) custodians is adequate for purposes of collecting custodial documents in relation to entities solely involved at the finished dose level.

5. Mylan Pharmaceuticals Inc.

Mylan and Plaintiffs have been working cooperatively and productively toward the finalization of an ESI custodians list. Initially, those efforts focused on the identification of individuals in Mylan's global operations and its API production facilities. As of December 4, the parties have agreed to 27 such custodians and, while discussions are ongoing, that list is nearing completion and should be finished in advance of the December 11 hearing. Also, with the benefit of the Court's recent Order, Dkt. 303, the parties are engaged in the meet-and-confer process with respect to the identification of custodians on the finished-dose level. Although those discussions are not as advanced as the API and global operations, Mylan anticipates that the parties will be able to reach an agreement by December 18.

IV. Plaintiffs' Proposed Search Terms Should be Modified Because they Include Overbroad Terms and Terms Designed to Find Documents that this Court has Already Deemed Not Discoverable.

As currently drafted, Plaintiffs' list of proposed search terms includes many terms that are overbroad on their face and 18 terms meant to fish for evidence of spoliation. As more specifically described below, Manufacturer Defendants ask that the Court exclude 18 spoliation terms, exclude 31 overbroad terms that are beyond repair, and modify the remaining overbroad terms in the manner proposed below.

The overbroad terms will obviously be found in documents related to all of the other drugs manufactured by the Manufacturer Defendants and would therefore result in a disproportionately large number of non-responsive documents that Manufacturer Defendants' attorneys will be required to sift through at an immense expense. Manufacturer Defendants seek the Court's assistance in avoiding this unnecessary cost and delay by modifying most of these overbroad terms and excluding the rest. Most of these overbroad terms can be cured by requiring that documents containing such terms must also contain a term linking the document to valsartan.[13] The remaining overbroad terms—those that cannot be cured and therefore should be excluded—consist of:

1. 7 terms that are (a) overly generic on their face and (b) cannot be cured by additional limiting terms, and

2. 26 terms that (a) are overly generic on their face because Manufacturer Defendants are drug manufacturers and (b) cannot be cured by additional limiting terms.

The overbroad terms that Manufacturer Defendants seek to modify are acceptable terms if modified. In fact, through the meet and confer process, the parties were eventually able to make a number of well-crafted modifications to meet the needs of all parties. The above-described four categories of terms—that is, (a) those relating to spoliation; (b) those requiring narrowing; (c) those that are overly generic; and (d) those that are overly generic given the context—are the only remaining categories in dispute. To assist the Court in visualizing these four categories, Manufacturer Defendants have attached Exhibits J and K hereto. As will be explained more thoroughly below, these Exhibits contain Plaintiffs' search terms (Exhibit J) and modifier terms (Exhibit K). Manufacturer Defendants have color-coded these terms, as explained herein, to identify the four categories of documents in dispute.

[13] More specifically, if documents containing these over broad terms also contain one of the following terms, then Manufacturer Defendants do not object to the term: *Valsartan*, amlodipine*, Diovan*, Exforg*, HCT, HCTZ, sartan, or sartans.

A. Procedural History

Plaintiffs initially proposed 351 search terms to use in searching the Manufacturer Defendants' custodial data (e.g., emails, documents on local server drives, documents on hard drives). Of these 351 search terms, Plaintiffs proposed that 64 terms should be run on all of the custodial data of each of the Manufacturer Defendants (the "Standalone terms"). Each document containing at least one Standalone term would be subject to review for responsiveness to Plaintiffs' document requests. Plaintiffs further proposed that the remaining 287 terms should be run along with 92 modifier terms, which we will refer to as "modifiers." Each document containing (A) at least one of these 287 terms and (B) at least one of the 92 modifier terms would be subject to review for responsiveness to Plaintiffs' document requests. Each document determined to be responsive to Plaintiffs' document requests would then be subject to privilege review and would be produced if not privileged. Privileged documents would be withheld or redacted and would be logged as privileged.

The parties participated in multiple lengthy meet and confers. Manufacturer Defendants made multiple proposals to modify the search terms in order to limit the potential for false positives[14] and in order to decrease the chances that the terms will result in primarily nonresponsive documents. At the conclusion of this process, Plaintiffs have settled upon 485 search terms and 96 modifiers.[15] Plaintiffs anticipate adding further when they receive the names of each of Manufacturer Defendants' manufacturing facilities. This increase in number was not all bad; part of the increase was attributable to the Manufacturer Defendants' request that Plaintiffs break up certain terms instead of using wildcards, and these changes helped to reduce the potential for false positives. Another part of the increase stems from the addition of a long list of names of FDA Inspectors. The rest of the increase is comprised of Plaintiffs' newly added terms.

Both the search terms and the modifiers are broken up into various categories. Of the 485 (primary) search terms on Plaintiffs' current list, 76 are Standalone terms and the remaining 409 are grouped into separate categories that Plaintiffs propose to run along with specific categories of the 96 modifiers. The 485 search terms can be found in Exhibit J to this letter and the 96 modifiers can be found in Exhibit K to this letter. A copy of each Excel spreadsheet will be provided to the Court by email.

The name of each modifier category appears on each separate list of modifiers. Each category of search terms identifies the intended search string to be run for each term. For example, for each term in the "Regulatory" category of search terms, the intended search string is: "<term>

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[14] A false positive is when a search term hits within a document but not for the meaning for which that term was intended.

[15] Many of Plaintiffs' "primary" search terms appear as a string of terms connected by "**or**" connectors. In calculating the total search term and modifier counts here, we counted each of the terms separately.

AND (<drug name> or <solvents> or <regulatory modifiers> or <facility names>)." This means that each document containing the term and at least one of the modifiers in any of the four modifier categories listed will be a document that must be reviewed by the Manufacturer Defendants.

B. Neither the facts nor the case law support Plaintiffs' argument that the Court should adopt its search terms list wholesale.

Plaintiffs advised that they intend to argue to this Court that their list of proposed search terms should be approved by the Court in full because the Manufacturer Defendants have not collected data in order to calculate the financial burden that would result from implementing Plaintiffs' proposed searches. While it is agreed that custodial data has not been collected, Plaintiffs' argument should be rejected because custodians have not been finalized and because Manufacturer Defendants' challenges to Plaintiffs' list of proposed search terms are based entirely on case law that does not require a showing of burden.

In a large case involving many custodians, until custodians and relevant time-periods are agreed upon or decided by the court, a preliminary, partial collection and searching of electronic data for the sole purpose of running test searches would be costly and wasteful. Here, it was expected that Plaintiffs would propose additional custodians and that custodians initially proposed by Defendants could be rejected in favor of alternatives proposed by Plaintiffs. Indeed, Plaintiffs ultimately proposed hundreds of additional custodians. These additional custodians were proposed long after the time when Plaintiffs suggest that the Defendants should have collected the data of its initially proposed custodians. Even now, it is still not clear which custodians will be in the final set approved by the Court, and any collection, processing, and searching of any proposed custodians' data would be an extraordinarily expensive and inefficient way to test search terms for burden. *See Arconic Inc. v. Novelis Inc.*, No. 17-1434, 2019 U.S. Dist. LEXIS 195213, *60 n.9 (W.D. Pa. Sep. 6, 2019) (determining that the collection, processing, and searching of the data of merely proffered custodians would be an extraordinary expensive and inefficient way to determine if a proposed custodian's data is cumulative of other custodians). This is particularly true here. Since the Manufacturer Defendants proposed their initial custodian lists, the parties have briefed, and the Court has ruled, on issues which both limited and expanded the scope of permissible discovery. For example, the Court has limited the relevant time period for custodial discovery on each Manufacturer Defendant, but held that discovery into certain aspects of the finished dose manufacturing process is also appropriate.

Further, such costly and wasteful practices would not be probative of burden. Even if the Manufacturer Defendants had collected the data of the initial custodians they each proposed and then loaded a sample date range of documents into a search platform to conduct test searching, any hit counts on that data cannot be meaningfully extrapolated to additional custodians or to additional time-periods. Different employees handle different issues in different volumes, and even the same employee will handle different issues over the course of time. It would be misleading to the Court to argue that the volume of documents containing one or more of Plaintiffs' search terms for certain

custodians during certain time-periods could be extrapolated to other employees and other time-periods.

While conflicts regarding search terms ordinarily would not arise until after issues regarding custodians and relevant time-periods are resolved, here, the Court has sought to resolve all discovery issues by a date certain. Time-periods were determined only recently and custodians are yet to be determined. Consequently, the Manufacturer Defendants are unable to calculate the precise financial burden that would result from Plaintiffs' proposed search terms. They can, however, show (*see* Section C below) that of the hundreds of search terms proposed by Plaintiffs, a significant number are objectionable under Rule 26 as overly broad on their face. Manufacturer Defendants can also show (*see* Section D below) that certain of Plaintiffs' terms are designed to find documents relating to spoliation—something that this Court has explicitly determined not to be at issue at this stage.

Contrary to Plaintiffs' all-or-nothing argument regarding the Manufacturer Defendants' inability to prove burden, courts do exclude search terms that are overly generic (without a showing of burden), either because they are facially broad terms or because the terms are rendered overly generic in light of their usage in the business of the party whose data is being searched. Such determinations may be made by this Court without a showing of financial burden because "overly generic" search terms cut against the "principles of proportionality" under Rule 26, "recent amendments [to which] place greater emphasis on this important principle." *Diesel Power Source v. Crazy Carl's Turbos*, No. 2:14-826, Dkt. 74 (D. Ut. Jan. 5, 2017); *see also Diesel Power Source v. Crazy Carl's Turbos*, No. 2:14-826, 2017 WL 721995, at *2 (D. Ut. Feb. 23, 2017); *Digital Ally, Inc. v. TASER International, Inc.*, No. 16-2032, 2018 WL 4334297, at *2 (D. Kan. Sept. 11, 2018). This is the very same reasoning used by the Court in its order on macro discovery issues in limiting certain discovery because "the burden and expense of [that particular] discovery is disproportional to its importance and relevance." 11/20/19 Tr. at 16:5–17:5.

C. A substantial portion of Plaintiffs' proposed search terms are overly broad and should be either modified by linking them to the products at issue or excluded entirely.

1. Background

Through the meet-and-confer process described above, Plaintiffs and the Manufacturer Defendants have agreed on a number of search terms and search term strings. Those terms are marked with green highlighting in the attached **Exhibits J** and **K** and include particular ANDA and DMF numbers on the Standalone terms list and the names contained in the "Authors and Inspectors" list. First, Plaintiffs represent that the ANDA and DMF numbers are connected to valsartan and are therefore self-limiting; second, Plaintiffs represent that the FDA inspector names should not be limited by the drug names because many of the inspectors were inspecting Defendants' facilities and manufacturing practices rather than any particular drugs. The Manufacturer Defendants accept these representations and do not seek to limit those terms using the drug names.

The Manufacturer Defendants are amenable to implementing searches based upon the vast majority of the remaining proposed search terms, but only to the extent those terms are limited by the addition of valsartan-related drug names as required modifier terms. Such terms, though overbroad on their face, are curable under such circumstances. Some examples of these terms are described in Section (C)(2) below, and all of these terms are marked with purple highlighting in **Exhibit J**.

Still, there are some terms among those proposed by Plaintiffs that are of such a generic nature that they should be excluded from the list altogether because, even if limited by the valsartan-related drug names, they would be likely to result in large numbers of non-responsive documents. These terms, some of which are identified and explored in subsection (C)(3) below, are marked with blue and red highlighting in the attached **Exhibits J** and **K.**

2. Certain Generic Search Terms Should Be Narrowed by Mandatory "Drug Name" Modifiers

Simply put, this case is about valsartan contamination—in particular, how, why, when, and where certain lots of the drug became contaminated with certain specified impurities. As such, and particularly in this day and age, Plaintiffs' entitlement to discovery of ESI should be limited accordingly, as "emergence of e-discovery only has intensified the need for judicial scrutiny of the scope of delivery[.]" *Sterling Heights*, 2015 U.S. Dist. LEXIS 19356, at *8; *see also Digital Ally*, 2018 WL 4334297, at *2 ("Defendant's inclusion of many **generic** and **commonly used** words … as search-term combinations renders Request 2 **overly broad on its face**. …The **lack of any further narrowing search criteria for these commonly used words**, such as linking them with other more unique terms **such as a product … name**, makes ESI Request 2 overly broad on its face." (emphasis added)); *see also L-3 Communications Corp. v. Sparton Corp.*, 313 F.R.D. 661, 670 (M.D. Fla. 2015) ("Defendants' analogy between searching an electronics design and manufacturing firm for 'DOE' (short for 'design of experiment') and 'Quality Management System' to **searching a law firm for 'pleading' on a law firm's servers seems** an apt one. Absent significant narrowing, the expansive search terms proposed by Plaintiff will not do." (emphasis added)).

Here, though, because Plaintiffs' search terms read like a composite of common words and phrases in the pharmaceutical manufacturing industry, *see* **Exhibits J** and **K**, it is clear that implementation of those terms and search strings—in their current forms—would yield ESI wholly unrelated to valsartan (let alone ESI unrelated to *discoverable* valsartan-related information). For example, consider just two of the Standalone terms proposed by Plaintiffs: (1) **moiety or moieties** and (2) **"voluntary action indicated**." Running a search for **moiety or moieties** without any modifiers restraining the search to the subject matter of this case would unearth mountains of documents most of which would likely be entirely unrelated to valsartan; pharmaceutical manufacturers, like Manufacturer Defendants, deal with, document, and discuss moieties—molecule components responsible for activating a physiological or pharmacological effect of a given drug substance—as a matter of course on a routine basis. Equally expansive would be a search for **"voluntary action indicated"** (i.e., which would unearth any document referencing, for example,

a voluntary request from any regulatory agency) or for any of the other search terms marked in purple in the Standalone terms list contained in **Exhibit J**. These searches, without some tethering to this case, are mere shots in the dark.

Although the Manufacturer Defendants submit that the Court would be well within its right to exclude these sorts of terms, some of the search terms proposed by Plaintiffs—specifically, those marked with purple highlighting in **Exhibit J**—need not be excluded altogether if they are sufficiently narrowed to reach the relevant subject matter of this case. To facilitate this, the Manufacturer Defendants have proposed mandatory drug name modifiers to prevent unruly searches from veering far outside the bounds of relevant discovery. In particular, the Manufacturer Defendants ask that the Court require each of the search terms marked in purple highlighting in **Exhibit J** to be run with, in addition to those modifiers proposed by Plaintiffs, the mandatory modifier ***Valsartan* or Diovan* or Exforg***. At Plaintiffs' request, the Manufacturer Defendants are willing to expand this list to also include **amlodipine* or HCT or HCTZ or sartan or sartans**. This full list of modifiers is labeled "Drug Names" by Plaintiffs and is included in **Exhibit K.**

Critically, although Plaintiffs apply the "Drug Names" modifiers to all but the Standalone terms, the Drug Names are joined with many other categories of modifiers only with the "**or**" connector, such that the "Drug Names" are simply additional modifiers to *expand* the scope of the search rather than *limit* the search. The Manufacturer Defendants propose the use of the "**and**" connector, which would mandate that **only** documents containing at least one of the "Drug Names" could be generated by the search. A simple example demonstrates the difference one connector can make in the search string: the search **A and (1 or 2)** is quite different from, and more expansive than, **A and 1 and 2**; the latter example only permits documents that contain A and **both** 1 and 2; the former expands the world of potentially generated documents by reaching material that includes either or both of the modifiers.

The proposed term **(cGMP* or (current pre/5 manufacturing) or GMP*)**—referencing "current good manufacturing practices"—provides a good example of the propriety (and necessity) of the Manufacturer Defendants' proposal. Certainly, the concept of cGMP is relevant to the issues in this case. However, given their proposed manner for searching for the term, Plaintiffs have taken an otherwise justifiable search request out of the realm of relevance. As a result, searches performed based on their proposals may well "divert the parties' resources and attention away from the core issues in dispute." 11/20/19 Tr. at 17:2-5.

Specifically, Plaintiffs request that a search be run for: **(cGMP* or (current pre/5 manufacturing) or GMP*) AND (<regulatory modifiers> OR <inspect> OR <drug names> OR <solvents> OR <manufacturing modifiers> OR <medical modifiers> OR <facility names>)**. In this case, Plaintiffs propose running the cGMP against at least[16] scores of modifiers (in the alternative). Again, although "drug names" are included as *possible* modifiers, they are not *mandatory* modifiers (given use of the "**or**" connectors as opposed to the "**and**" connector). Thus,

[16] The terms under "Facility Names" are still to be determined.

a search performed using this proposed search string would turn up documents containing cGMP and ***any*** one of the more than scores of modifiers to the right of "**AND**"—even if the document has nothing to do with valsartan. For instance, the above search, unless restricted as proposed, will register a hit for any document containing **cGMP** and **FDA**;[17] or **cGMP** and **recall**;[18] or **cGMP** and **NIH**,[19] etc., even if none of the generated documents have anything to do with valsartan.

The cGMP term is just one of many—marked in purple highlighting in **Exhibit J**—for which the same result can be expected. Performing these searches with the terms and modifiers as formulated by Plaintiffs will generate the documents responsive to Plaintiffs' document requests, but they would also, in a sweeping and uncalculated fashion, scoop up the same types of documents related to each and every drug manufactured by each and every Manufacturer Defendant. Set aside the fact that "the right to even plainly relevant discovery is not limitless[,]" *Novartis AG*, 2016 WL 7178602, at *4, Plaintiffs' proposed searches would turn up untold numbers of documents concerning non-valsartan drugs, which the Court has already determined are, save few exceptions, not discoverable in this case. *See* Dkt. 303, at 3; 11/20/19 Tr. at 16:6 – 17:5. The result would be a multiplication of the number of potential documents to be reviewed by at least the number of drugs manufactured by each Manufacturer Defendant.

While the proposed search terms are overbroad as written, the deficiency with respect to most of the terms can be cured by adoption of Manufacturer Defendants' proposed mandatory modifier as follows, with Defendants' suggestions in **blue**:

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[17] The FDA maintains a full website section dedicated to cGMPs. *See* FDA: *Facts About the Current Good Manufacturing Practices (CGMPs)* (June 25, 2018), *available at* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps. As such, Plaintiffs' above-described proposed search would yield this particular document—entirely irrelevant to the issues in this case—if it were among the data of a given custodian, because it contains both **cGMP** and **FDA**.

[18] Plaintiffs' search would also register the documents cited in the previous footnote as it also contains both **cGMP** and **recall.**

[19] The website run by the US National Library of Medicine, NIH, also maintains a document concerning cGMPS. *See Velagaleti, Ranga, et al*., NIH: *Impact of current good manufacturing practices and emission regulations and guidances on the discharge of pharmaceutical chemicals into the environment from manufacturing, use, and disposal*, 2002 Mar. ENVIRON HEALTH PERSPECT. 110(3), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240759/. As such, Plaintiffs' above-described proposed search would yield this particular document—entirely irrelevant to the issues in this case—if it were among the data of a given custodian, because it contains both **cGMP** and **NIH**.

> (cGMP* or (current pre/5 manufacturing) or GMP*) AND **(<drug names>) AND** (<regulatory modifiers> OR <inspect> OR <solvents> OR <manufacturing modifiers> OR <medical modifiers> OR <facility names>).

This proposed search, as modified by Defendants, would generate cGMP documents relevant to the issues in this case given that it would be tailored to the product at issue in this case.

Plaintiffs initially agreed that many of these search terms should properly be subject to Defendants' proposed limitation and, at one point, even agreed to review their list of terms to identify those terms they believe **should not** be so modified. Instead, Plaintiffs provided the current proposal using an "**or**" connector between the "drug names" modifiers and the remaining modifiers. (Set aside the fact that the resulting proposal is untenable for the reasons described above, this sort of gamesmanship should not be rewarded.)

Beyond merely being imprecise, Plaintiffs' submission of its proposed search terms, as written, seems to disregard the fact that the issue of relevance and discoverability of documents pertaining to other drug products has already been briefed and ruled upon by the Court, which **denied** Plaintiffs' requests to discover non-valsartan drugs. *See* Dkt. 303, at 3. More specifically, in announcing its decision at the November 20, 2019, Case Management Conference, the Court stated:

> The Court is skeptical that any materially relevant information will be gleaned from non-Valsartan discovery that will not be learned from the Valsartan discovery.
>
> Thus, the burden and expense of the non-Valsartan discovery is disproportional to its importance and relevance. The same is true for other processes using the same solvents at issue in this case.
>
> . . .
>
> Discovery directed to other sartans' processes, testing and solvents will divert the parties' resources and attention away from the core issues in dispute.

11/20/19 Tr. at 16:6–17:5.

If required to use Plaintiffs' proposed search terms in their present form, each of the Manufacturer Defendants would be required to pay attorneys to needlessly comb through hundreds of thousands of documents that have already been deemed irrelevant by the Court, only to then determine that those already-deemed-irrelevant documents are not relevant and should not be produced. This superfluous exercise would "bog down" the discovery process in this matter and result in an immense burden falling squarely and unnecessarily on Manufacturer Defendants. *See Enslin*, 2016 U.S. Dist. LEXIS 193556, at *8 (explaining that there "is no obligation on the part of

a responding party to examine every scrap of paper in its potentially voluminous files" (internal quotation marks and citations omitted)). Especially given that the Court has already ruled that certain categories of documents are not discoverable, all parties to this MDL—including the Court hosting it—would benefit from avoiding the unnecessary delay that would necessarily result from Plaintiffs' proposed search terms in their present form.[20]

L-3 Communications is instructive here. There, the court recognized that the plaintiff's proposed search terms would yield documents on products manufactured by the defendant other than those at issue in the case. *See* 313 F.R.D. at 669. Even though the court agreed that the defendant's "application of manufacturing standards in 'other, similar contexts'" were discoverable, the court still found the plaintiff's product-neutral search terms problematic:

> The **benefits of Plaintiff's forays into discovery about unrelated products are likely to be relatively limited. Most information about unrelated products is likely to be completely irrelevant, and what is relevant is unlikely to have great probative value**, relative to information about the [products at issue]. Because the expected benefit of the discovery Plaintiff seeks is limited, the Court will not compel Defendants to respond to Plaintiff's requests in this area where responding would expose Defendants to disproportionate expense.

Id. (emphasis added). Thus, even where the court **agreed** that discovery into other products was warranted, it **still** rejected the "forays into discovery about unrelated products" as proposed by the plaintiff's submitted search terms. *See id*. Against this backdrop, and especially because the Court has **denied** Plaintiffs' attempts to obtain discovery on non-valsartan drugs, implementation of Plaintiffs' proposed search terms—unless restricted in the manner proposed by Defendants—would be wholly improper.

The fact is that without "narrowing search criteria for these commonly used words, **such as linking them with other more unique terms such as a product … name**," Plaintiffs' proposed search terms described in this section and marked in purple in **Exhibits J** are overly broad. *Digital Ally*, 2018 WL 4334297, at *2. Instead of excluding these "curable" search terms, Manufacturer Defendants merely request that the Court simply do what it has already said it would—"reasonably

[20] This already significant burden would become absurd if the Manufacturer Defendants were required to search to records of the nearly 200 individuals that Plaintiffs seek to add as custodians. For example, as explained in the section on custodians, many of ZHP's employees are not assigned any particular drug. Search terms that are not valsartan-specific will return mountains of documents related to the approximately 30 other APIs that ZHP manufacture, not to mention the additional finished dosage products—which will require significant attorney time to filter out from the responsive documents.

limit plaintiffs' discovery in order to prevent duplicative, cumulative, and minimally important discovery[,]" 11/20/19 Tr. at 18:12-4, by, in this case, imposing reasonable guardrails to train the document discovery on relevant information and keep it from veering into that which the Court has already decided is neither relevant nor discoverable.

3. Notwithstanding Application of "Drug Name" Modifiers, Certain Search Terms Proposed by Plaintiffs are Incurably Generic and Overly Broad and Should be Excluded.

Even with Manufacturer Defendants' proposed inclusion of the "Drug Names" modifiers to rehabilitate certain search terms that would otherwise have been indefensibly overbroad, some search terms remain so generic that they must be excluded from the search process. As described above, "overly generic" search terms cut against the "principles of proportionality" under Rule 26, "recent amendments [to which] place greater emphasis on this important principle." *Diesel Power Source*, Dkt. 74; *see also Diesel Power Source*, 2017 WL 721995, at *2 ; *Digital Ally*, 2018 WL 4334297, at *2.

Defendants have identified 31 terms that are either irredeemably deficient as simply overbroad in the classic sense or overly generic in the context of the parties from whom discovery is sought in this case: pharmaceutical manufacturers. The former category of classically overbroad search terms is marked in blue, and the latter category of terms that are overly generic given the context are marked in red, in **Exhibits J** and **K.**

In *Diesel Power Source*, the court took issue with—and rejected as "overly generic"—the search terms "Turbo" and "Tech" (among others) in a lawsuit between businesses that manufacture and produce diesel products and services, and whose products are marketed as increasing the horsepower and performance of customers' vehicles. *See id*., *passim*. In *Digital Ally,* the court classified a set of search terms as "overly broad on its face" given the terms' common usage in the plaintiff's trade. *See* 2018 WL 4334297, at *2.

In *Webasto Thermo & Comfort North America, Inc. v. BesTop, Inc.*, the court similarly rejected certain search terms submitted by the defendant as overly broad given the nature of the plaintiff's business: "The overbreadth of other terms is **obvious, especially in relation to a company that manufactures and sells** convertible tops: 'top,' 'convertible,' 'fabric,' 'fold,' 'sale or sales.'" 326 F.R.D. 465, 468 (E.D. Mich. 2018) (emphasis added) ("many of [the defendant]'s terms are indeed overly general on their face."). Likewise, in *L-3 Communications*, the court recognized the overly broad nature of certain search terms offered by the plaintiff, given the nature of defendant's trade. *See* 313 F.R.D. 661, 670 (M.D. Fla. 2015) (rejecting as overbroad a requested search for "DOE" (short for "design of experiment") from an electronics design and manufacturing firm. *See* 313 F.R.D. at 670. Most recently, in a lengthy Report and Recommendation on discovery disputes arising in *Arconic Inc. v. Novelins Inc.*, Special Master Faith Hochberg took issue with the plaintiff's submission of "alum*" as a search term in an antitrust case involving price-fixing by an aluminum manufacturer:

> "alum*" is an overly-broad search term to use to search for alternative pretreatments. **Novelis is an aluminum company. It manufactures a wide variety of aluminum products**, for a range of sectors. It is unreasonable to ask an aluminum manufacturer to search for all discussions of aluminum in a case relating to a specific sub-set of that company's operations.

No. 17-1434, 2019 WL 5802365, at *23 (W.D. Pa. Sept. 6, 2019) (emphasis added).

The following seven search terms proposed by Plaintiffs should be excluded as overly generic on their face: **alert***, **inadequate***, **fail***, **heat**, **problem***, **quality***, and **unknown***. Even when paired with the modifiers proposed by Plaintiffs (contained in **Exhibit K)** and even if limited by the Drug Names as proposed by Manufacturer Defendants, the overbreadth of these terms is obvious given their common use. These terms are not narrowly tailored to pick up documents discussing any particular issue in this case, and any relevant documents that happen to contain any of these terms are highly likely to be picked up by one of the terms on Plaintiffs' extensive list of terms. As such, like the words dissected and rejected in *Digital Ally*, these terms, commonly used in relation to matters wholly unrelated to the issues in these proceedings, should be rejected. *See* 2018 WL 4334297, at *2.

Other proposed search terms and "modifiers"[21] are generic and overbroad given the context of this case and the nature of the parties from whom discovery is sought, i.e., manufacturers of pharmaceutical drugs. On that basis, the Manufacturer Defendants take issue with the following 19 proposed search terms marked in red in **Exhibits J** and **K: inspect***, **investigat***, **observation***, **warn***, **abnorm***, **bioequiv***, **complain***, **hazard***, **observation***, **risk***, **toxic***, **expir***, **repack***, **re-pack***, **resal***, **resell***, **temperature**, **yield***, and **onset***, as well as the following five proposed modifiers **Agency**, **inspect***, **FDA**, **regulat***, and **test**, on the grounds that they are overly generic and should be excluded in light of Defendants' trade.

A term such as **bioequiv*** is a textbook example of a generic term in the context of generic drug manufacturers—akin to or even more nonspecific than proposing the term **pleading** as a search term in litigation involving a law firm. *See L-3 Communications*, 313 F.R.D. at 670. Specifically, all generic drugs are necessarily subject to bioequivalence studies in order to compare two different preparations of a drug and determine whether they result in the same end product. Accordingly, all of the Manufacturer Defendants will have countless documents related to bioequivalence of various drugs. Further, even with the modifiers offered by Plaintiffs (which themselves include generic terms like **acid***, **test***, **Agency**, and **FDA**, and thus do close to nothing to narrow the search) and even after limiting with Drug Names, terms like **expire** or **expiration** (as would result from a search

[21] Although modifying terms ("modifiers") may serve a limiting purpose by narrowing the scope of a given search, when stitched together with "**or**" rather than "**and**," such modifiers in fact serve as alternative, potential pairings—that is, responsive documents *may* contain any one of those modifiers, but need not contain any more than one.

for **expir***) or **observation** or **inspect*** or **temperature** reflect the vernacular for pharmaceutical manufacturers, and are thus bound to be omnipresent among their records. These terms are as generic to the pharmaceutical manufacturing industry and thus to Manufacturer Defendants' businesses as are "Turbo" for diesel product manufacturers; "fabric" for convertible manufacturers; "DOE" for electronics manufacturers; or "aluminum" for aluminum manufacturers. *See Diesel Power Source*, 2017 WL 721995, at *2; *Webasto*, 326 F.R.D. 465, 468; *L-3 Communications*, 313 F.R.D. 661 at 670; *Arconic*, 2019 WL 5802365, at *23. Just as the obviously generic terms were rejected as overly broad in those respective cases, the obviously generic words and phrases proposed here—as formulated by Plaintiffs—should face a similar fate.

As mentioned above, the terms with modifiers proposed by Plaintiffs fare no better; consider the proposed search **observation* AND (<drug names> or <solvents> or <regulatory modifiers> or <facility names>)**. Ostensibly simple, this search is comprised of the following Boolean logic:

> **observation* AND (*Valsartan or amlodipine* or Diovan* or Exforg* or HCT or HCTZ or sartan or sartans or *azide* or *formaldehyde* or *-N3* or *xylene* or acid* or aqueous* or chloramin* or HNO2 or hydrochlor* or N-3* or NaNO* or tolute* or (Tributyl* or TIN) or (Triethyl* or TEA) or (zinc /3 chloride) or ZnCl* or ("Abbreviated New Drug Application" or ANDA) or (CDC or "Centers for Disease Control") or (CDER or "Center for Drug Evaluation and Research") or (DEA or "Drug Enforcement Administration" or "Drug Enforcement Agency") or ("Environmental Protection Agency" or EPA or USEPA or "US-EPA" or "1200 Pennsylvania Avenue") or "Food and Drug Administration" or FDA or USDFA or "US-FDA" or "College Park") or ("NIH or "National Institutes of Health")**.[22]

This essentially untethered yet representative search proposal, which is not even the most expansive proposed by Plaintiffs, would unearth any document containing both **observation** and **FDA**; or **observation** and **NIH**, a problem (a) arising from the reality that Plaintiffs' proposed search terms are generic; and (b) compounded by the fact that the search query, like many others proposed by Plaintiffs, *see* **Exhibits J** and **K**, combines a generic phrase on the one hand with an extensive list of similarly generic words and phrases linked together with **or** instead of **and**. As such, despite the long list of terms seemingly narrowing the search, ***only one*** of the words or phrases following the term **observation*** need be found in a document in order for that document to be a hit, and thus this search—like others—would generate documents related to every drug manufactured by each of the Manufacturer Defendants, a universe of material that dwarfs that which is actually relevant in this case.

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[22] In fact, the scope of this search is even more expansive than shown here because, based on Plaintiffs' proposal, the final set of modifiers is a list of facility names that has not yet been created.

For these reasons, Manufacturer Defendants request that the Court exclude from ESI discovery those search terms proposed by Plaintiffs that are marked in blue and red in **Exhibits J** and **K.**

D. Terms meant to fish for spoliation evidence should be excluded for the reasons this Court has already explained.

At the November 20, 2019, macro discovery hearing, the Court flatly rejected the Plaintiffs' suggestion that they have evidence that the Defendants engaged in spoliation. *See* Nov. 20, 2019, Tr. at 17:25 – 18:2. Undeterred, the Plaintiffs insist upon the inclusion of search terms whose only apparent purpose is to continue their fishing expedition for "spoliation," but which are otherwise irrelevant to this litigation. The rules of discovery, however, do not require the Defendants to collect and review documents based on nothing more than the Plaintiffs' rank speculation.

Specifically, the Plaintiffs have proposed seventeen (17) primary search terms (grouped into 7 search strings) that, on their face, have no relevance to the issues in this case. Those terms are marked in orange highlighting in **Exhibit J** and are replicated below:

- (bottle pre/2 lies) or Eban
- bury or burie* or conceal*
- "cover up*" or coverup* or "cover-up*"
- crash* or disaster*
- delet* or destroy* or remov* or trash* or shred*
- hide* or suppress*
- whistleblow*

Tellingly, Plaintiffs initially proposed these search terms in relation to their claim that the Defendants have spoliated evidence. In support of that allegation, the Plaintiffs relied upon several FDA inspection documents that they put before the Court during macro discovery briefing on the issue of whether Defendants' litigation holds are discoverable. The Court denied the Plaintiffs' demand, specifically finding that the Plaintiffs' proffered documents do not evince spoliation. *See* Nov. 20, 2019, Tr. at 17:25 – 18:2 ("The Court agrees now with what it said then. The Court does not find that plaintiffs have as yet made a case that spoliation occurred in this case."). Having hit a dead end on spoliation, Plaintiffs have pivoted and now assert that the very same search terms that were originally intended to ferret out spoliation are, instead, necessary to locate documents concerning the Defendants' compliance with Current Good Manufacturing Practices ("cGMP"). But this brief chronology serves to confirm that the Plaintiffs' supposed interest in discovering "cGMP documents" through the application of these search terms is nothing more than an attempt to circumvent the Court's determination that there is no predicate basis for discovery on the issue of spoliation.

Furthermore, as shown by the first of term in the above list, these search terms are a fishing expedition based on the book *Bottle of Lies* by Katherine Eban. As Defendants raised to this Court in July, Plaintiffs cite repeatedly—and inappropriately—to this book throughout their Master Complaints. 7/24/19 Tr. at 4:12–22. Defendants requested permission to strike those paragraphs from the complaints out of a concern that "when we get to discovery requests, if we haven't had some kind of ruling, we're going to have to be fighting with Your Honor about" discovery "about some issue totally unrelated" to these actions that Plaintiffs raise "because it was in a book." *Id.* at 12:17-22. In response, the Court stated that such an unfounded request would be "[d]enied." *Id.* at 12:23.

This Court has previously observed that "while the standard of relevancy is a liberal one, it is not so liberal as to allow a party to roam in the shadow zones of relevancy and to explore matter which does not appear germane merely on the theory that it might become so." *Justiano v. G4 Secure Solutions, Inc.*, 291 F.R.D. 80, 83 (D.N.J. 2013) (internal citations omitted). Further, "[f]ishing expeditions during which a party searches for evidence to support claims or defenses not yet pleaded are not permitted." *Dix v. Total Petrolchemicals USA, Inc.*, No. 10-3196, 2011 WL 5513185, at *3 (D.N.J. Nov. 10, 2011) (internal citations omitted). Indeed, "[t]he discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable without discovery, not to find out if it has any basis for a claim." *Claude P. Bamberger Int'l, Inc. v. Rohm & Haas Co.*, No. 96-1041, 1998 WL 684263, at *2 (D.N.J. Apr. 1, 1998) (quoting *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1326 (Fed. Cir. 1990)).

Simply put, the Plaintiffs' newly-formulated position that these search terms relate to cGMP is purely pretextual. In reality, what they want—and what they freely admitted before they lost the macro discovery argument—is to conduct a fishing expedition for evidence of spoliation. Moreover, Plaintiffs do not even agree to limit this baseless inquiry to valsartan-containing products. Rather, Plaintiffs would have the Manufacturer Defendants run these search terms across their entire document collections without meaningful limitation. This is the epitome of overbroad discovery, as there is presently no indication that any Manufacturer Defendant has engaged in the conduct that Plaintiffs allege. Thus, because the Plaintiffs have failed to provide a credible explanation why the Manufacturer Defendants should collect and review documents based on these search terms, the spoliation-related terms marked in orange highlighting in **Exhibit J** should be excluded.

V. Plaintiffs have failed to "sharpen their pencils" and narrow their requests as the Court has instructed.

The Manufacturer Defendants are prepared to produce documents in accordance with their Amended Objections to Plaintiffs' First Set of Requests for Production of Documents and the Court's rulings on the "macro" discovery issues. On November 29, 2019, Plaintiffs served a set of Amended Requests for Production on the Manufacturer Defendants. By email dated December 3, the Court commented on these Amended Requests, noting, "Plaintiffs need to sharpen their pencils regarding what they specifically want." Plaintiffs agreed to serve a revised set of Amended Requests for Production and sent this second set of Amended Requests at 3:00 p.m. on December 5.

Defendants are currently evaluating this second set of Amended Requests based on each Defendant's Amended Objections and Responses, the Court's rulings on the "macro" discovery issues, and the agreements reached through the meet and confer process. Notably, Plaintiffs appear to have done little to "sharpen their pencils" to more specifically tailor their document requests. *See* Exhibit L. Plaintiffs' revisions are minimal and generally limited to incorporating the Court's rulings. This Court has already observed that Plaintiffs' Requests for Production directed to the Manufacturer Defendants were "general and overbroad . . . [and] facially inappropriate," 11/20/2019 Tr. at 12:10-12, and Plaintiffs have made little headway in articulating more narrow requests.

Despite the fact that the Manufacturer Defendants are still in the process of evaluating Plaintiffs' second set of Amended Requests, having received them only hours before submitting this filing, the Manufacturer Defendants are using this opening brief to raise certain discrete issues that they have already identified as being in dispute. It is clear Plaintiffs are still requesting documents that are in direct contravention of the Court's ruling on the macro discovery issues and subject to Defendants' amended objections, and while evaluating the Amended Requests in light of the parties' meet and confers Defendants maintain their amended objections and do not waive them with respect to either the original Requests for Production or the Amended Requests. Defendants reserve the right to object to any and all of the Amended Requests served on December 5 and will address additional issues, including those Plaintiffs raise in their opening brief and others identified by Defendants upon additional review of the second set of Amended Requests, by way of the response on December 9.

A. Production of Withdrawn or Unapproved ANDAs is not proportional to the needs of the case, largely cumulative of core discovery already produced, and outside the scope of this litigation as articulated by the Court at the November 20, 2019 hearing and in the Court's November 25, 2019 Order.

The Court's November 25th, 2019 Order (Dkt. 303) regarding "macro discovery" issues resolved numerous differences between the parties and clarified the scope of discovery in this litigation. Repeatedly, the Court emphasized that the focus of discovery in this case is Valsartan API and Valsartan products sold in the United States. The Court limited the facilities at issue to those which manufactured products for sale in the United States, *id.* ¶ 2, and denied Plaintiffs' requests for foreign regulatory documents and foreign sales, marketing materials, and agreements, with limited exceptions, *id.* ¶¶ 6-7. In so doing, the Court stated that "[t]he case involves sales of Valsartan in the United States and that is where the focus of plaintiffs' discovery should and will be." 11/20/19 Tr. At 20-21. To the extent Defendants are in possession of documents reflecting the actual or potential presence of nitrosamines in another sartan product prior to July 2018, the Court's order carves out several exceptions where Defendants are required to locate and produce such documents. *See* Dkt. 303 ¶¶ 4, 6-7.

During meet and confers following the Court's November 25th Order, Plaintiffs have several times asked Defendants to commit to producing ANDAs which were either withdrawn or are currently unapproved. In either case, the documents at issue necessarily relate to products which

were never sold in the United States, much less purchased or taken by any of the Plaintiffs in this litigation. Such ANDA documents clearly lie outside the scope of discovery.

Any legitimate bases for which Plaintiffs might seek these documents are already covered by the existing document productions and the Court's order. First, withdrawn ANDA materials will likely be duplicative of the ANDA materials Plaintiffs have already received in core discovery. Second, should the withdrawn/unapproved ANDA files contain "documents reflecting the presence of any nitrosamine in any sartan product made prior to July 2018," *see* 11/20/19 Tr. at 17, "documents regarding potential or actual nitrosamine contamination prior to July 2018" sent or received from any foreign regulatory body, *see* Dkt. 303 ¶ 6, or "documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan," such documents are already covered by the Court's order, *id.*.

During the meet and confer process, Defendants pointed to this language from the Court and advised that all of the relevant document types potentially contained within the withdrawn/unapproved ANDAs will be produced to Plaintiffs. Defendants objected and continue to object to production of complete ANDA files for products not associated with nitrosamine contamination as not proportional to the needs of the case. Moreover, these files—the unapproved ANDAs in particular—contain highly sensitive proprietary information and shed no further light on the parties' claims or defenses in this litigation. Other than the documents which the Court has already ordered Defendants to produce, Plaintiffs fail to articulate any legitimate reason for production of these withdrawn or unapproved ANDAs. Accordingly, Defendants ask the Court to order that such files are outside the scope of discovery, subject to the caveats previously articulated at the November 20, 2019 conference and in the November 25, 2019 Order.

B. Plaintiffs' demand for sales and pricing data reflecting, to the dollar, each and every contract, transaction, negotiation, and communication from the sourcing of raw materials for API all the way through retail sales is irrelevant and disproportionate to the needs of this litigation.

It is difficult to imagine a broader demand for sales and pricing information than that submitted by Plaintiffs in their Requests for Production to Defendants:

> **REQUEST NO. 101**: ***Produce all documents relating to valsartan sales you made in the United States to any purchaser (including, but not limited to, wholesalers, distributors, retailers and retail consumers), including documents that reflect total gross sales, total net sales, total number of units sold, unit price (gross and net), unit cost, cost of goods sold, profit margin, NDC, batch number, and lot number, on an annual basis, by, defendant, state, territory or the District of Colombia.***

But they one-up themselves at Request No. 103, wherein they insist that Defendants also produce—on a *worldwide* basis—"[a]ll documents and communications relating to negotiations over price and terms of sale or distribution between any defendant and any purchaser or re-seller of

valsartan," and then again at Request No. 105, seeking "all documents relating to any arrangements between you and any other person or entity that did, could, or may affect the quantity or price of valsartan purchased." And, in the event it wasn't already captured, Plaintiffs separately request "all documents relating to contracts for the sale of valsartan" at Request No. 109.

However, these pale in comparison to the coup de grâce at Request No. 107:

REQUEST NO. 107: ***For each month from January 1, 2010 to the present, produce all documents relating to your actual and projected valsartan sales, including:***

- ***a. List price;***
- ***b. Average marginal price;***
- ***c. Average wholesale price;***
- ***d. Wholesale acquisition cost;***
- ***e. Direct price;***
- ***f. Average discount off of wholesale price or wholesale acquisition cost;***
- ***g. Price under Medicare program;***
- ***h. Price under Medicaid program;***
- ***i. Maximum allowable price;***
- ***j. Average manufacturing price (AMP) as defined by, and reported to, the Centers for Medicare and Medicaid Services;***
- ***k. Best price, as defined by, and reported to, the Centers for Medicare and Medicaid Services;***
- ***l. Net revenue;***
- ***m. Gross sales;***
- ***n. Net sales;***
- ***o. Units;***
- ***p. Gross shipments;***
- ***q. All measures of margin, income, earnings, and profits;***
- ***r. Unit of volumes sold;***
- ***s. Unit of volumes sold net of returns;***
- ***t. Total product contribution;***
- ***u. All costs and expenses attributable to the product;***
- ***v. Sales and distribution cost;***
- ***w. Cost of goods sold;***
- ***x. Manufacturing costs;***
- ***y. Marketing, advertising, promotional, and sales expenses;***
- ***z. Depreciable and capital improvements;***
- ***aa. Regulatory compliance;***
- ***bb. Short-run average variable costs;***
- ***cc. Long-run average variable costs;***
- ***dd. Fixed costs;***
- ***ee. Materials cost;***

ff. Labor cost;
gg. Marginal cost;
hh. Rebates, discounts, vouchers, or other product promotions, returns, or charge-backs; and
ii. Coupons or co-pay cards.

All of this, in a case where the crux of the economic class Plaintiffs' damages claim is that they are entitled to the recovery of the price they paid for finished-dose valsartan. *See* Dkt. 121, at *ad damnum* clause, ¶ E. In this context, Plaintiffs' requests are facially and patently irrelevant and far beyond anything that might be required in this litigation. Indeed, when the Court conducted a preliminary review of Plaintiffs' Rule 34 discovery and offered feedback by email on December 3, 2019, the sales, pricing, and distribution demands at Request Nos. 88–109 were among those singled out by Judge Schneider as "low hanging fruit" and as a prime example of an area where Plaintiffs need to sharpen their pencils to explain what they "genuinely need."

In response, Plaintiffs' counsel vowed to "modify the requests as needed to ensure they comply with the guidance provided by" the Court. Nonetheless, during a subsequent meet and confer on December 3, Plaintiffs refused to narrow their sales and pricing demands, insisting that they are entitled not only to the hard data reflecting pricing and costs, but also the underlying contracts, communications, and negotiations. As of the time this brief was filed, Plaintiffs had failed to abide by their promise to modify the sales and pricing requests.

Accordingly, Defendants stand on their objections to the sales and pricing requests as irrelevant and disproportionate to the needs of this litigation. Moreover, the fact remains that the manufacturing Defendants do not have visibility regarding the claimed damages—basically, the out-of-pocket price paid by a Plaintiff for valsartan. This information is more likely to come from the Plaintiffs themselves, who presumably know what they paid for a prescription. The only possible justifications Plaintiffs have for needing any pricing information is to build a class-wide damages model or for an actual or exemplary damages calculation in the economic class case. As the Court has already instructed, Plaintiffs have to demonstrate the specific categories of sales/pricing information "genuinely needed" to make such calculations. And even then, any pricing information necessary for actual/exemplary damages should wait until such time as liability has been established as to a particular Defendant.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

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